

Issued September 27, 1911.

# United States Department of Agriculture,

## OFFICE OF THE SECRETARY.

---

### NOTICE OF JUDGMENT NO. 1056.

(Given pursuant to section 4 of the Food and Drugs Act.)

---

#### ALLEGED MISBRANDING OF A DRUG PRODUCT—"ANTIKAMNIA TABLETS."

In July, 1910, the United States Attorney for the District of Columbia, acting upon the report by the Secretary of Agriculture, filed in the Supreme Court of the District of Columbia a libel praying condemnation and forfeiture of 100 packages of a drug product called "Antikamnia Tablets" in the possession of the Washington Wholesale Drug Exchange, Washington, D. C.

Examination of samples of this product by the Bureau of Chemistry of the United States Department of Agriculture showed it to contain among other ingredients, acetphenetidin, a derivative of acetanilid. The libel alleged that the product was offered for sale in the District of Columbia and was misbranded in violation of the Food and Drugs Act of June 30, 1906, and was therefore liable to seizure for confiscation. Misbranding was alleged because the product contained as one of its ingredients acetphenetidin, and the label failed to bear a statement that said ingredient was a derivative of acetanilid, and further because the label was false and misleading in that it bore the statement that the product contained no acetanilid, thereby implying that no quantity or proportion of any derivative of acetanilid was contained therein. Thereupon, the Antikamnia Chemical Co. entered its appearance as owner, excepting and objecting to the allegations of the above libel, and praying that the said libel be dismissed and the product be restored to the claimants.

On November 18, 1910, the cause came on for hearing and the court rendered its opinion sustaining the exceptions of the claimants and ordering the dismissal of the libel.

CLABAUGH, Chief Justice:

Now, gentlemen, in accordance with the views stated to counsel here, the opinion of the court is sought purely as to the question whether or not, under this Food and Drugs Act, it is essential, where any of the drugs, and more particularly in this case, acetanilid, is used,—whether it is essential to place upon the label not only the name of the derivative of the parent drug, but also a further statement upon the label that it is the derivative of the parent drug. That is really the question at issue. In other words, in this case the label bore the name of this acetphenetidin, and was labelled correctly, so far as the amount of it contained in the package is concerned, the only question being whether it ought further to have stated that it is the derivative of acetanilid, or words to that effect, and the question therefore arises whether or not the label in the case contains all that is sufficient under this Act.

Now in this case the Government has labelled the various packages, upon the theory that the law requires, in conjunction with the regulations of the three Secretaries, the further statement of the fact that it is the derivative of this acetanilid.

Now a good deal of the argument in this case was spent upon the question as to whether or not the act in question was a penal statute, or merely a remedial one; that is: was it a quasi-criminal act, or purely a remedial act?

The only question here, in my judgment, is this: Does the act under which these proceedings have been taken, require the statement, where the name of the derivative is given—does that act require the further statement placed upon the label that it is the derivative of some given drug mentioned in this given section of the act; in this case, of acetanilid? Now the act specifies these various drugs that are mentioned in this particular section, and to read that portion of it that is material, it seems to me, the law says: “Or, second: If the package fail to bear a statement on the label of the quantity or proportion of any alcohol \* \* \* or acetanilid, or any derivative, or proportion of any such substance contained therein.” Now the act further provides that these three Secretaries shall have the right to make all needful and necessary regulations for the purpose of carrying into effect this act. Now, in that view of the case, the respective secretaries mentioned in the act did provide regulations, which regulations said, among other things, that it was essential for the manufacturers to place upon the label the derivative, and to show not only that it was a derivative, but shall further add to that the drug from which it is a derivative; in other words, the parent thereof. Is it within the scope of the authority of these secretaries, therefore, to add regulations compelling that addition, or is that legislation upon their part, and therefore beyond the scope of their right or authority?

Now I have spent a good deal of time, gentlemen, in considering this case. Everyone, I suppose, at least the general public is disposed to regard this act as of great benefit and use to the public, and it ought to be upheld in every particular, if it is possible so to do. Now briefly stating what is conceded in the brief of the Government, and fairly conceded, and to which there can be no dispute, and that is, that the secretaries cannot add anything to the law, that is, make an addition to an act that has already made its provisions; they cannot provide anything that will become an additional law in the construction of that act. So that it is a pretty narrow question, and one that, it seems to me, is not so much a question of authority, as purely a question of interpretation of this act.

Now conceding, for the purposes of the statement of this case, that this is not a quasi criminal statute, but is purely a remedial one. If that be true,

then it is the duty of the court to so construe it as will give effect to the purposes and objects for which it was passed, and I have no doubt that the secretaries could, with the same propriety, make regulations that would the more effectually carry into execution the purpose and intent of the law makers. That being so, what is the fair construction of the act, and does it not need interpretation? Now the right to interpret an act in conformity with the purposes and object of that act simply means that where the act itself is not perfectly clear, then they can give such an interpretation to it as will carry out and gratify the purposes of its passage.

An interpretation does not, as I understand it, mean that you can add anything to language which is plain. If there is anything about the language of a statute which annuls the purposes of that statute, then you have the right to interpret according to its purposes, if there be the slightest doubt about the words of the act; but if the act is plain, and the words present no difficulty, then, it seems to me, you cannot interpret or put something else in, because, perhaps, it would have been plainer or 'broader in its effect than the simple words of the act. I do not mean that you have got to indulge in the interpretation of the letter of the law, but the spirit, of course; otherwise we would have a very exceedingly narrow condition concerning the law. We must always interpret by the spirit of the law. What does this law say? Reading it again: "Or, second, if the package fail to bear a statement on the label of the quantity or proportion of any acetanilid, or any derivative or proportion of any such substances contained therein." Now if it fail to state that it is acetanilid, if it fails to state that it is a derivative, that is, the name of anything derived from acetanilid, if it fails to state what the name of that derivative is, then it brings it within the penalties of the act. Now, as I understand it, this label that they have on the packages states the name of the derivative—acetphenetidin is the name of the derivative which is stated upon there—and the amount that is contained in the package is likewise stated. Now what is to suggest that it should go any further? It is argued that the very title of the act implied the demand of something else, and that title is, from the libel by the Government, "An act for preventing the manufacture, sale, transportation of adulterated, or misbranded, or poisonous or deleterious foods, drugs, medicines and liquors, and for regulating the traffic therein, and for other purposes." Now is it for the purpose of preventing the manufacture, sale etc.?

Now that is the purpose of it. It is to protect the community from being imposed upon by packages having one brand, when indeed the contents of them are entirely different from the character of brand that may be imposed upon anybody. It is suggested that it is likewise to prevent the drug habit, as it has been described in the argument, and it is to be gathered from the argument, as I understand, when the act was passed; so that at all events it is done for the protection of society, for the protection of the people, and when we come to the consideration of the act itself, we have the law stating that you shall truly brand, you shall truly label any article that you are selling. Now they are selling this acetphenetidin, and this package is branded as that. Now why, or what there is in the act which would say, or which would require to be stated that this acetphenetidin is the derivative of acetanilid, is certainly not apparent upon the face of either the title or the reasons for the act. When the court cannot assume that the people generally are any more familiar with acetanilid than they would be with this acetphenetidin, how can the court say that, as a matter of law, one may be just as familiar with the statute as the other. The court cannot give its own personal views on the subject, that it knew more about this acetanilid than it did of these derivatives. The purpose

of the act is to state to the person who makes this drug that you must truly state to the people what it is. Now how can they be informed, unless the court takes judicial knowledge of something that it seems to me would be certainly doubtful, to say the least, that the people at large are any more familiar with one thing than the other? Furthermore, I don't see that it adds to it one way or the other, by labelling in this way, as it is suggested.

It would be very much more safe to a community, it seems to me, if the secretaries who have the right to pass regulations for the carrying of this law into effect, had passed an act which said: Wherever the derivative of acetanilid is to be used—either acetanilid or its derivative—either the manufacturer shall place upon the label that it is a poisonous drug, or a dangerous drug, and that it should not be taken in doses of over five grains, say. Now that would effect the purposes of this act in a proper way; it would advise the people at large that acetphenetidin is a dangerous drug; that it ought not to be taken in doses of over five grains, say for illustration. That would give notice to the people that it was a dangerous drug, but would it be contended that under this act the secretaries could force the placing of such a statement upon the label? Surely that would not be for the purpose of carrying into effect an act, but it would be adding legislation to the act, because it would be requiring something that the act did not require. For some reason or the other I would assume that the druggist or manufacturer who put these things up did not feel compelled to put these things on the label. It would be a good thing to protect the people, but unless some such suggestion was made in the act, how can the secretaries, with the authority only to suggest regulations as would carry into effect the act—how can they undertake to say that in addition to what the law says, that he place upon the label from what parent drug it is derived? If they can say that, they can also say: You must put upon that label the statement of the character of the drug. That would manifestly be a positive addition to the law which requires the name of the drug to be placed upon the label, though such action on their part would be very much more effective to advise the people that it is a dangerous drug, than merely to say it is a derivative of acetanilid.

Now when this case was argued—and we are taking the whole argument together—it occurred to me that it was very similar to that decided by the Supreme Court of the United States in 166 U. S., in respect to the importation of stallions. Here, under the act, they were authorized to bring into this country from some place abroad, free of duty, any stallion, if it was for breeding purposes. That was the act. What was the reason of that? The reason was that it would improve the stock in this country. It could have had no other reason. Here you are allowed to bring foreign bred stallions into this country for breeding purposes, and the only reason for that would have been because the foreign-bred stallion was supposed to be better, and would improve the breed of horses in this country. I cannot imagine any other reason. It was not certainly because we wanted more. That would be a useless thing, because we certainly had all of the character of the horse that we needed for breeding purposes, but it was manifestly for the purpose of improving the breed of horse in this country. Now, to carry out that purpose, the Secretary of the Treasury says: Here, inasmuch as this act is passed for the purpose of improving the breed of horse in this country, why we will, in accordance with our rights, make any necessary regulations to carry into effect that statute; we will pass a regulation that before you can bring him in, you must show that the stallion is of superior breed, and they refused to permit a stallion to be brought in until it was shown that it was of a superior character or breed of

horse. Now they refused, therefore, when the party to that cause sought to have this horse brought in without the payment of any duty. The Secretary says no, you have not shown him to be a superior breed, and the result was that it went to the Supreme Court of the United States, and the court says: The Secretary of the Treasury had nothing to do with it. The law says that any stallion could be brought in for breeding purposes; it did not say whether it should be superior or not. And consequently the court held that the Secretary had exceeded his rights; that he had added something to the law.

I have read the other cases, but that case seems to me to put into a nutshell the point of view that I am trying to impress here. I have read all the authorities suggested and some others, but it seems to me that it comes back to the simple question: "Did this act need any interpretation, or was it perfectly plain, and if it needed such interpretation, could that interpretation add anything that Congress required to be done? Now this is the way that question seems to be answered here. I don't think the act needs any interpretation, because it is perfectly plain as to what it said, and evidently as to the purposes for which it was said. Then, from the other standpoint, if they have added anything to the law that should be placed upon that label, they have exceeded their rights. Now, in my opinion, they have added something. \* \* \* Therefore, I think the exceptions in this case ought to be sustained.

From this decision the United States appealed to the Court of Appeals of the District of Columbia, where the judgment of the lower court was affirmed.

The opinion of the Court of Appeals is as follows:

SHEPARD, C. J.

This is an appeal by the United States from a judgment sustaining exceptions to, and dismissing a libel.

The libel prayed the seizure and condemnation of one hundred packages of a certain drug describing the same as follows:

"Twenty packages, more or less, of said drug, labelled and branded as follows: "Antikamnia Tablets, Contain 305 grains of acetphenetidin, U. S. P. per ounce, Guaranteed by the Antikamnia Chemical Company, under the Food and Drugs Act, June 30th, 1906, U. S. Serial Number 10. The Antikamnia Tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, codein, heroin, cocaine, alpha or beta eucaine, arsenic, strychnine, chloroform, cannabis indica, or chloral hydrate. Antikamnia Tablets five grains. One ounce Antikamnia Tablets. Manufactured in the United States of America by the Antikamnia Chemical Company St. Louis, U. S. A."

Also seventy other packages, more or less, of said drug, labelled and branded as follows: "Antikamnia and Codein Tablets. Contain 296 grains acetphenetidin, U. S. P. per ounce. Contain 18 grains suppl. codein per ounce. Guaranteed by the Antikamnia Chemical Company, under the Food and Drugs Act, June 30th, 1906, U. S. Serial No. 10. The Antikamnia and Codein Tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, heroin, cocaine, alpha or beta eucaine, arsenic, strychnine, chloroform, cannabis indica, or chloral hydrate. One ounce Antikamnia and Codein Tablets. Manufactured in the United States of America by the Antikamnia Chemical Company, St. Louis, U. S. A."

Also ten other packages, more or less, of said drug labelled and branded as follows: "Antikamnia and Quinine Tablets. Contain 165 grains acetphenetidin, U. S. P. per ounce. Guaranteed by the Antikamnia Chemical Company, under

the Food and Drugs Act, June 30th, 1906, U. S. Serial No. 10. The Antikamnia and Quinine Tablets in this original ounce package contain no acetanilid, antifebrin, antipyrin, morphine, opium, codein, heroin, cocaine, alpha, or beta eucaine, arsenic, strychnine, chloroform, cannabis indica, or chloral hydrate. One ounce Antikamnia and Quinine Tablets. Manufactured in the United States of America by the Antikamnia Chemical Company of St. Louis, U. S. A."

The libel charges that the packages of said drugs are subject to condemnation as misbranded in violation of the provisions of the Food and Drugs Act, approved June 30th, 1906.

"Because each and all of said packages of drug contain a large quantity and proportion of acetphenetidin, which your libelant charges is a derivative of acetanilid, and that under the provisions of the said Act of Congress and of the regulations lawfully made thereunder, it is provided and required that the label on each of said packages should bear a statement that the acetphenetidin contained therein is a derivative of acetanilid; and yet your libelant charges that each and all of said packages fail to bear a statement in any form that the acetphenetidin contained therein, is a derivative of acetanilid, or that the drug contains any derivative of acetanilid.

"Your libelant further charges that each and all of said packages of drug are further misbranded in that the labels thereon are false and misleading, for the reason that each and all of the said labels bear the statement that no acetanilid is contained therein, and that said statement imports and signifies that there is no quantity or proportion of any derivative of acetanilid contained in said drug."

Under the warrant ordered to issue, the Marshal seized ninety three packages, in all, bearing the labels aforesaid. By leave of the Court, the Antikamnia Chemical Company, alleging itself to be the owner of the packages was permitted to appear as party defendant.

The exceptions on which the libel was dismissed are substantially: That the Act does not require that the label on each of said packages shall have a statement that the acetphenetidin contained therein is a derivative of acetanilide, nor is it necessary under said Act that a derivative of any parent substance should state that it is a derivative of such substance, provided the derivative itself is named by its proper name. That the statement on the packages that it contains no acetanilid is neither false nor misleading, but true, and the libel while charging that acetphenetidin is a derivative of acetanilide, does not charge that there is any acetanilide in acetphenetidin.

Section 1 of the Food and Drugs Act makes it unlawful to manufacture within any territory, or the District of Columbia, an article of Food or Drug which is adulterated or misbranded, "within the meaning of this Act," and imposes a penalty therefor.

Section 2, prohibits the introduction into any State or territory, or the District of Columbia, and the shipment from the same to any other State territory, etc. or foreign country, any article of food or Drug, in the original packages, adulterated or misbranded within the meaning of this Act, and the sale or offer for sale in the District of Columbia or territories of any such adulterated or misbranded foods or drugs; and provides a penalty therefor.

Section 3, provides: "That the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce and Labor shall make uniform rules and regulations for carrying out the provisions of this Act, including the collection and examination of specimens of foods and drugs," etc.

Section 4 provides for the examination of foods and drugs, and the giving of notice if found to be adulterated or misbranded.

Section 5 makes it the duty of the District Attorney to whom report shall be made of any violation of the Act, to cause appropriate proceedings to be commenced, without delay, for the enforcement of the penalties provided in the Act.

Section 6 defines the meaning and inclusion of the terms drug and food.

Section 7 declares that for the purposes of this Act an article shall be deemed to be adulterated: "In case of drugs: First: If when a drug is sold under or by a name recognized in the United States Pharmacopœia, or National Formulary, it differs from the standard of strength, quality, or purity, as determined by the test laid down in the United States Pharmacopœia, or National Formulary, official at the time of investigation; Provided that, no drug defined in the United States Pharmacopœia, or National Formulary, shall be deemed to be adulterated under this provision if the standard of strength, quality or purity be plainly stated upon the bottle, box, or other container thereof, although the standard may differ from that determined by the test laid down in the United States Pharmacopœia, or National Formulary.

Second, if its strength or purity fall below the professed standard, or quality under which it is sold." (Other portions of the Section relate to Confectionery and Foods.)

Section 8. "That the term 'Misbranded' as used herein, shall apply to all drugs, or articles of food, or articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein, which shall be false or misleading in any particular, and to any food or drug product which is falsely branded as to the State, Territory or Country in which it is manufactured or produced. That for the purposes of this Act an article shall also be deemed to be misbranded: "In case of drugs: First, If it be an imitation of, or offered for sale, under the name of another article. Second, If the contents of the package as originally put up shall have been removed in whole or in part, and other contents shall have been placed in such a package, or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any substances contained therein." (Remainder of Section applies to Foods.)

Section 9 relates to guaranties by wholesalers, jobbers and manufacturers.

Section 10, provides for the seizure and condemnation of adulterated, or misbranded foods, drugs and liquors through proceedings instituted for the purpose, which proceedings "shall conform, as near as may be, to the proceedings in admiralty, except that either party may demand trial by jury of an issue of fact joined in any such case, and all such proceedings shall be at the suit of, and in the name of the United States."

Sections 11, 12 and 13, have no possible bearing on the questions involved.

Acting upon the recommendation of the Commission of experts, the Secretaries of the Treasury, of Agriculture, and of Commerce and Labor, respectively, adopted certain rules and regulations for carrying out the provisions of the foregoing Act, on October 17th, 1906, and published the same.

Regulation 28 was amended to take effect on April 1, 1910. This states the derivatives of the several drugs enumerated in Section 8 and names the several preparations containing them respectively. Derivatives of or from, and preparations containing acetanilide, are enumerated as follows:

Acetanilide (Antifebrine, Phenylacetamide).

Derivatives: Acetphenetidine, citrophen, diacetanilide, lactophenin, methoxyacetanilide, methylacetanilide, para-iodoacetanilide, and phenacetine.

Preparations containing acetanilide or derivatives: Analgesics, antineuralgics, antirheumatics, cachets, capsules, cold remedies, elixirs, granular effervescent salts, headache powders, mixtures, pain remedies, pills and tablets.

The regulation concludes as follows: In declaring the quality or proportion of any of the specified substances the names by which they are designated in the act shall be used, and in declaring the quantity or proportion of the derivatives of any of the specified substances, in addition to the trade name of the derivative, the name of the specified substance, shall also be stated, so as to indicate clearly that the product is a derivative of the particular specified substance.

1. A preliminary contention on behalf of the appellants is, that the Act being remedial and not penal, should be liberally construed. This contention seems to be of little or no practical importance in the present case, as the substantial question presented is one of power rather than construction. Without discussion, therefore, it may be conceded that the Act, while it contains penal provisions without which it could not be enforced, was enacted to remedy the great mischief resulting from the unrestricted sale of adulterated drugs and articles of food and ought to be given, where possible, a construction that will effect the general legislative intention.

2. The substantial questions for determination arise upon two propositions that have been submitted in support of the contention of error in the dismissal of the bill on the exceptions stated. The first of these is: That the packages of the drug are misbranded, because the labels fail to recite that acetphenetidine contained therein is a derivative of acetanilide.

It seems clear that this omission is not in express violation of the requirement of Section 8 of the Act, for the reason that the label states the true name of the drug—acetphenetidine, which, though, not one of those specifically named in the Section, is a derivative of one of them—acetanilide.

Now, while persons skilled in chemistry and pharmacy would know that acetphenetidine is a derivative of acetanilide, it is certain that the average purchaser and user of drugs would not. For this reason, no doubt, the Commission of expert chemists, whose recommendations were adopted by the three secretaries, suggested the regulation requiring the label of a derivative of one of the drugs specified in Section 8 to show not only the trade name of the same, but also the name of the substance of which it is a derivative. It is well settled that where an Act of Congress has for its object the raising of revenue, the administration of the affairs committed to an executive department, as of the public lands, and the like, or the execution of the power over commerce, matters of detail looking to the promulgation of regulations for carrying the law into effect, as, for example providing for the proceedings thereunder, the fixing of standards, brands and labels, or the ascertainment of necessary facts upon which the law may operate, may be expressly delegated to an executive officer. In such instances Congress legislates on the subject as far as is reasonably practicable, and from the recognized necessities of the case is compelled to leave to executive officers the duty of bringing about the result pointed out by the Statute. (*U. S. vs. Bailey*, 9 Pet., 239; *U. S. vs. Caha*, 152 U. S., 211; *In re Kollock*, 165 U. S., 526; *Field vs. Clark*, 143 U. S., 470; *Union Bridge Co. vs. U. S.*, 204 U. S., 364; *St. L. & I. M. Ry. Co. vs. Taylor*, 210 U. S., 281; *Bong vs. Campbell Art Co.*, 214 U. S., 236; see also *Coopersville Co-operative Creamery Co. vs. Lemon*, 163 Fed. R., 145; *Prather vs. U. S.*, 9 App. D. C., 82; *Kollock vs. U. S.*, 9 App. D. C., 420.)

On the other hand, it is equally well settled that the power conferred to make regulations for carrying the law into effect must be exercised within the powers



delegated, that is to say, confined to details for regulating the mode of proceeding to carry into effect the law as it has been enacted by Congress. It cannot be extended to amending, or adding to the requirements of the Act itself. (*Morrill vs. Jones*, 106 U. S., 466; *U. S. vs. Symonds*, 120 U. S., 46; *U. S. vs. Eaton*, 144 U. S., 677; *Williamson vs. U. S.*, 207 U. S., 425.)

The decisions cited mark the general boundary line between the powers that may be delegated to administrative officers and those that may not be. It remains to determine on which side of that line the power claimed in the present case falls.

It must be borne in mind that the Food and Drugs act does not confer upon executive officers the power to prescribe the forms of brands and labels upon drugs, as was done by the Oleomargarine Act, that was considered in *Kollock's Case*, *supra*. The only power conferred is that, in Section 3, which provides that the three Secretaries named, "shall make uniform rules and regulations for the carrying out of the provisions of this Act, including the collection and examination of specimens of food and drugs." etc. \* \* \*

Section 8 declares when an article shall be deemed to be misbranded: "First: If it be an imitation of, or offered for sale under the name of another article." "Second: If (among other things) the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha, or beta eucaine, chloroform, cannabis indica, chloral hydrate, or any derivative or preparation of any such substances contained therein."

In so far as the regulation designates the several derivatives of the drugs enumerated in Section 8, and the preparations containing the same, we are of the opinion that it is within the power conferred in Section 3 to make uniform rules and regulations for carrying out the provisions of the Act. It was not reasonably practicable for Congress to ascertain and declare these several derivatives and preparations, which might then have existed, much less to anticipate those, which might later come into existence and use. Having declared that the quantity or proportion of the several derivatives of the named drugs shall be stated on the labels, the ascertainment of such derivatives was a matter of detail properly confided to the executive officers in carrying out the provisions of the law. The regulation having named acetphenetidine as a derivative of acetanilide, the manufacturer complied therewith to the extent of naming the proportion of said derivative contained in the antikamnia tablets, but did not comply with the requirement of the same that it should also recite that it was, in fact, a derivative of acetanilide. The last requirement was, in our opinion, an amendment of, or an addition to the Act itself, and therefore beyond the powers of the Executive authority. Congress reserved to itself the statement of the contents of the labels and did not require that when a drug was a derivative, merely, the name of the drug from which derived should also be recited. Had it intended that this should be done, it would have so declared distinctly. In this respect the case is clearly differentiated from *In re Kollock*, *supra*, and comes within the rule governing the second class of cases before recited, including *U. S. vs. Eaton*, 144 U. S., 677-688; and *Williamson vs. U. S.* 207 U. S., 425-462. In the case last cited, the question was whether a false oath made in final proof required by a regulation of the Commissioner of the Land Office constituted perjury. The statute made certain requirements in regard to preliminary proofs and reiterated some of them in the section relating to final proofs, but omitted the one, which by the regulations made by the Commissioner under the power conferred by the Act to give effect to its provisions, was required. It was held that the power to adopt rules and regulations for the enforcement of the Act could not be construed to warrant one that was in fact an addition to the Act.

Since the submission of this case, the Supreme Court of the United States has rendered a decision, the opinion in which, delivered by Mr. Justice Lamar, clearly draws the line between those powers which may be delegated by Congress to an executive officer and those which may not. (*U. S. vs. Grimaud*, May 1, 1911.) That was an indictment for violating a regulation of the Secretary of Agriculture relating to the use and occupancy of public forest reservations. It was said that in the nature of things it was impracticable for Congress to provide regulations for the various and varying details of the management of the forest reservations, and that it was within its power to authorize the Secretary to make such regulations as would secure the objects of such reservation, namely, to regulate the use and occupancy and preserve the forests from destruction. Having so done, it declared that "Any violation of the provisions of this Act, or such rules and regulations shall be punished as provided in Section 5388, R. S., as amended." The violation of such reasonable rules and regulations is "made a crime, not by the Secretary, but by Congress. The statute, not the Secretary, fixes the penalty." It is this feature of the Act that differentiated the case from *Williamson vs. U. S.*, *supra*, and other cases cited, which, in our opinion, furnish the rule of determination for the case at bar. Congress here prescribed what the labels should contain, and conferred no power upon the Secretaries to make a regulation adding anything thereto.

3. The second proposition is this in substance: the statement on the label that the drug "contains no acetanilide," is false and misleading, and constitutes misbranding within meaning of the Act. The libel does not expressly charge that acetphenetidine contains acetanilide. If it did, there would be no doubt of the soundness of the proposition, for the exceptions necessarily admit every fact plainly alleged. But it contains no such allegation. The charges that the labels are false and misleading "for the reason that each and all of said labels bear the statement that no acetanilide is contained therein, and that said statement imports and signifies that there is no quantity or proportion of any derivative of acetanilide contained in said drug." It is argued in support of the proposition that acetphenetidine, necessarily contains some appreciable quantity or proportion of the latter drug; and it is further argued that this is a matter of common knowledge of which the Court may take notice without proof. We cannot agree that it is a matter of common knowledge that a chemical derivative necessarily contains, or is of the same nature as the substance whence it may be derived. It was stated on the argument, without dissent, that very many well known substances, including acetanilide, are derivatives of benzene, or benzol. Some of these derivatives are nocuous, others entirely harmless. While, therefore, acetphenetidine is a chemical derivative of acetanilide, and may be derived therefrom in practice, it is in a general sense a derivative of Benzene or Benzol, and may, for all we know, be derived therefrom in actual practice for commercial use. When one wishes to ascertain the common meaning or signification of a word, resort is ordinarily had to the accredited dictionaries of the language. Murray's English Dictionary defines a chemical derivative thus: "A compound obtained from another, E. G. by partial replacement." The definition of the Standard Dictionary is substantially the same. In the latest edition of Webster's International Dictionary the following definition is given: "A substance so related to another substance by modification or partial substitution as to be regarded as derived from it, even when not obtainable from it in practice." These definitions do not carry us very far. About as far as common knowledge goes is that chemical changes occur in substances through the subtraction or the addition of some particular element. Sometimes the mingling of several substances having chemical af-

finities, but respectively innocuous, may produce a deadly poison. And sometimes the subtraction of an element from a poisonous substance may produce another that is perfectly harmless. The principles that direct these combinations and control the transformations affected are beyond common knowledge. They can only become known through the special study of the science of chemistry.

Whether, then, the addition or subtraction of elements through which acetphenetidin may, in theory or in practice be derived from acetanilide, produces such a chemical change of substance that it may be truly said to contain no acetanilide; or produces a substance which still contains an appreciable quantity or proportion of the same, presents a question of fact, which in our opinion, must be determined on the evidence of witnesses skilled in the science of chemistry.

To authorize the introduction of evidence an issue must be raised in the pleadings.

As before pointed out, the libel does not charge that the statement that the preparation contains no acetanilide is false, by reason of the fact that acetphenetidine does contain acetanilide. It carefully confines itself to the allegation that the statement is false because it does not recite that there is no quantity or proportion of any *derivative of acetanilide* contained therein. This clearly limits the charge of misbranding to the failure to state that acetphenetidine is a derivative of acetanilide. This is but another form of the complaint that the regulation has been violated. It does not raise an issue of fact as to whether acetphenetidine actually contains a perceptible quantity of acetanilide.

In accordance with these conclusions, the judgment will be affirmed.

From this decision an appeal will be taken to the Supreme Court of the United States.

JAMES WILSON,  
*Secretary of Agriculture.*

WASHINGTON, D. C., *August 9, 1911.*